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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/942,052

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EXAMINER

BLANCHARD, DAVID J

ART UNIT

PAPER NUMBER

1643

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/942,052

Applicant(s)

RAITANO ET AL.

Examiner

David J. Blanchard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 88-98 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 88-98 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-87 have been cancelled.
2. Claims 88-98 are pending are under examination.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

4. The rejection of claims 88-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al (Molecular Microbiology 27(1):171-186, 1998, previously cited on PTO-892 mailed 9/17/04) and in view of Campbell A. M. (Monoclonal Antibody Technology, Elsevier Science Publishers, NY, chapter 1, pages 1-32, 1986, previously cited on PTO-892 mailed 9/17/04) and Queen et al (5,530,101, 6/25/1996, previously cited on PTO-892 mailed 9/17/04) and Reiter et al (U.S. Patent 6,261,791 B1, 5/25/1999, previously cited on PTO-892 mailed 9/17/04) is maintained.

The response filed 3/3/2006 states that the art of Williams et al does not disclose the sequence of SEQ ID NO:728, but references Genbank Accession number AF025441, which contains an additional two amino acids at the N-terminus compared to SEQ ID NO:728. Applicant submits that Exhibit A in the previous Office Action is actually Genbank accession number BC015050, which was not submitted until October 1, 2001, which is after the priority date of the present application and as such is not available as prior art against the pending

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claims. Applicant concludes that because the sequence of Williams differs from the claimed sequence, this reference does not supply a critical portion of the Office's argument and as such the rejection fails to teach or suggest all the limitations of the claimed invention. This has been fully considered but is not found persuasive. The claims are directed to a protein comprising the amino acid sequence of SEQ ID NO:728 and antibodies thereto. Applicant is reminded that the term "comprising" is inclusive or open-ended and does not exclude additional, unrecited elements. See MPEP 2111.03. Thus, while the amino acid sequence of SEQ ID NO:728 is essential, the additional two amino acids in the sequence of Williams et al may be added and still form a construct within the scope of the claim. The examiner acknowledges applicant's remarks regarding Genbank accession number BC015050, however, as discussed supra, the polypeptide of Williams et al is identical to the protein comprising the amino acid sequence of SEQ ID NO:728 and reads on the claims.

Applicant criticizes the examiner's rejection as failing to articulate a *prima facie* case of obviousness because one of ordinary skill in the art would not have a reasonable expectation of success due to the two amino acid difference out of the total 229 amino acids of the polypeptide of SEQ ID NO:728 as taught by Williams et al. Applicant alleges that this two amino acid difference results in a protein having patentably distinct antigenic properties. Applicant cites Burgess et al and Lazar et al as evidence that protein chemistry is unpredictable and applicant alleges that the polypeptide of Williams et al with the two additional amino acids at the amino terminus would result in a protein that would fold

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differently from that of SEQ ID NO:728 and one of ordinary skill in the art would not have a reasonable expectation of success in producing an antibody that bound to SEQ ID NO:728 using the sequence taught by Williams. This has been fully considered but is not found persuasive. Although the art of Burgess and Lazar teach that minor changes in the amino acid sequence of a protein can have a dramatic affect on the biological characteristics of the protein, the polypeptide of Williams et al is identical to the polypeptide comprising the amino acid sequence of SEQ ID NO:728 instantly claimed and even considering the additional two amino terminal amino acids of the polypeptide of SEQ ID NO:728, applicant has not provided the requisite evidence to support the allegation of inoperability of the prior art. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. In re Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976).

In view that the polypeptide of Williams is 100% identical to the polypeptide comprising the amino acid sequence of SEQ ID NO:728 and 99% identical to the polypeptide consisting of the amino acid sequence of SEQ ID NO:728 (229/231 matches), one of ordinary skill in the art would reasonably conclude that antibodies against the polypeptide of Williams et al would also possesses the same structural and functional properties as those of the antibodies claimed. Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed antibodies with the antibodies of the prior art, the burden of proof is upon the Applicants to show an unobvious distinction between the structural and functional characteristics of the claimed

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antibodies and the antibodies of the prior art. See *In re Best*, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.). Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). See MPEP 2112.01. Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985).

Objective evidence, which must be factually supported by an appropriate affidavit or declaration to be of probative value includes evidence of inoperability of the prior art. See, for example, *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984). See MPEP 716.01(c). Applicant's have not presented any experimental data showing that the prior art antibody raised to the polypeptide comprising the amino acid sequence of SEQ ID NO:728 would not bind the polypeptide comprising the amino acid sequence of SEQ ID NO:728 instantly claimed. The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). See MPEP 716.01(c).

Applicant argues that there is no motivation to modify the prior art to achieve the claimed invention, i.e., there is no motivation to delete the two

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additional amino acid residues found at the amino terminus of the Williams et al article to arrive at SEQ ID NO:728. Applicant concludes that because Williams et al do not teach the same amino acid sequence as that recited in SEQ ID NO:728, the Williams reference does not support the instant rejection and none of Campbell, Queen et al and Reiter et al cure the deficiency of the Williams article. This has been fully considered but is not found persuasive. Applicant again argues with limitations not recited in the claims, i.e., the claims are not limited to SEQ ID NO:728. The term "comprising" is inclusive or open-ended and does not exclude additional, unrecited elements. See MPEP 2111.03. Thus, while the amino acid sequence of SEQ ID NO:728 is essential, the additional two amino acids in the sequence of Williams et al may be added and still form a construct within the scope of the claim.

For these reasons, the rejection is maintained.

Conclusions

5. No claim is allowed.
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory

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action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827



SHEELA HUFF
PRIMARY EXAMINER